REMARKS

Claims 1-50 are pending. Claims 1-34 were rejected. Claims 35-50 were withdrawn from consideration by the Examiner. Claim 30 was objected to by the Examiner. Claims 30 and 32 are amended. Claims 35-50 are canceled without prejudice or disclaimer of subject matter. Applicants reserve the right to file divisional applications directed to the canceled subject matter.

Accordingly, claims 1-34 will be pending upon entry of this amendment.

Claim 30 is amended to correct a typographical error which addresses the Examiner's objection. Claim 32 is amended to maintain consistency of language with claim 29 from which claim 32 depends. No new matter is added.

Objections to the Specification

Applicants thank the Examiner for the careful review of the specification. The typographical error at paragraph [00105] has been corrected by the present amendment to the specification. Reconsideration and withdrawal of the objection to the specification is respectfully requested.

Objections to the Claims

Claim 30 stands objected to as being dependent upon itself. Claim 30 has been amended to properly depend from claim 29, as suggested by the Examiner. Reconsideration and withdrawal of the objection to claim 30 is respectfully requested.

Double Patenting

Regarding the provisional obviousness-type double patenting over copending Application No. 10/790,312, Applicants respectfully submit that the instant application is now in condition for allowance, except for this outstanding rejection. Because this

application has a filing date (January 22, 2004) that is earlier than the filing date of copending Application No. 10/790,312 (March 1, 2004), Applicants respectfully request withdrawal of this rejection to allow the earlier filed patent application (the instant case) to issue.

Claim Rejections – 35 USC 102

Claims 1-4, 7, 13-15, 18 and 20 stand rejected under 35 USC 102(b) as being anticipated by Sparks et al. (US 5,354,556). Sparks describes a controlled release microparticulate powder that may be intimately admixed with at least one non-toxic polymer. (Claim 1)

The present invention, as described in claim 1, is drawn to a dry formulation, comprising ***at least two doses*** of ***coated*** drug particles having an average particle size of about 50 µm to about 600 µm, each ***coated*** drug particle comprising a core comprising a drug, and a hydrophobic polymer film coating at least a portion of the core. The dry formulation also comprises a viscosity enhancing substance in an amount effective to maintain the ***at least two doses*** of ***coated*** drug in a substantially homogeneous suspension for ***at least 24 hours*** at about 20°C to about 30°C, after combination with about 2 ml to about 60 ml of an aqueous liquid per dose of the coated drug and mixing in the presence of air.

For the reasons described below, Applicants respectfully submit that Sparks neither teaches nor fairly suggests the present invention.

Sparks does not teach at least two doses of drug particles in the dry formulation

At page 8 of the Office Action, the Examiner suggests that Sparks anticipates the claim limitation of at least two doses because the suspensions offer the possibility of twice-daily administration of a medicament.

Applicant is unable to find any teaching or suggestion in Sparks that would suggest that the suspension of Sparks, once formed, may be used for more than one

dose. As a matter of fact, Applicants urge that Sparks teaches away from the suspensions being stored for any period of time (e.g., for a second dose). As discussed above, Sparks is concerned with the formation of controlled release formulations. In making the formulation of Sparks, a polymer is admixed with the drug particle and suspended in a vehicle. This suspension was tested in Sparks for stability of dissolution. (See Table 3 at column 15) After 4 hours, there was about 80% dissolution of a theophylline suspension prepared according to Sparks. This clearly shows that the suspension of Sparks would not be useful for a second dose after, for example, four hours, as there would be about 80% dissolution of the polymer from the drug particles.

While Applicants agree that the 80% dissolution of theophylline may still permit a second dose of the drug, although, as discussed above, there is no teaching of using the Sparks formulation for more than one dose, such a second dose would clearly not exhibit the controlled release characteristics desired by the Sparks' formulation. Therefore, the present invention is both not anticipated nor rendered obvious by Sparks, as it is well established that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose (in this case, controlled release), then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) In the instant case, if Sparks is modified from a single dose suspension after mixing (as Applicants maintain that Sparks neither teaches nor fairly suggests any mixed suspension suitable for more than a single dose) to a multiple dose suspension, the doses following the first dose would lack the intended purpose of controlled release.

For the above reasons alone, Applicants respectfully submits that independent claim 1 is not anticipated by Sparks.

Sparks does not teach a dry formulation of coated drug particles

At page 7 of the Office Action, the Examiner suggests that Sparks teaches that the microparticles contain an active ingredient that is not entirely coated by the non-toxic polymer. For this teaching, the Examiner directs Applicant to claim 1 of Sparks.

While Applicant agrees with the Examiner's comment, Applicants respectfully submit that such language fails to teach or fairly suggest the present invention, which required the coated drug particle to have "a core comprising a drug, and a hydrophobic polymer film coating at least a portion of the core." Claim 1 of Sparks notes that the microparticles (drug particles, for example) are in intimate admixture with at least one non-toxic polymer, forming a micromatrix with the active ingredient uniformly distributed therethrough. The polymer of Sparks may partially surround the active ingredient to form the claimed micromatrix of Sparks, but Applicants fail to find any teaching or fair suggestion that Sparks teaches a coated drug particle with a core and a polymer film coating the core.

As a matter of fact, Applicants urge that Sparks teaches away from the core/polymer film coating structure instantly claimed. Sparks appears to require uniform distribution of the active ingredient within a micromatrix. Such a uniform distribution could not result in the core/polymer film coating as instantly claimed, as the active ingredient of the present invention forms the core which is coated by the polymer film.

For the above reasons alone, Applicants respectfully submits that independent claim 1 is not anticipated by Sparks.

Sparks does not teach maintaining a substantially homogeneous suspension for at least 24 hours

At page 8 of the Office Action, the Examiner suggests that the claim limitation of maintaining the suspension for at least 24 hours "is anticipated by Sparks because in the stability study of the suspension, samples were stored at room temperature and tested at 1, 2, 3, 4, 5, 6 and 24 hour time intervals over a period of 15 weeks."

While Applicants agree that Sparks did show a stability study of the suspension, Applicants respectfully submit that the results of this study do not teach or fairly suggest that a substantially homogeneous suspension may be maintained by Sparks over at least 24 hours. The stability study of Sparks showed that there was no ***chemical*** breakdown of the drug over 15 weeks. This fact, however, has nothing to do with

maintaining a substantially homogeneous suspension. Moreover, Table 3 at column 15 of Sparks shows nearly 100% dissolution of the theophylline suspension after 24 hours, suggesting that Sparks does not teach a substantially homogenous suspension being maintained for at least 24 hours as instantly claimed.

For the above reasons alone, Applicants respectfully submits that independent claim 1 is not anticipated by Sparks.

Applicants respectfully submit that, for the plurality of reasons described above, claim 1 is not anticipated by Sparks. Claims 2-4, 7, 13-15, 18 and 20, being dependent from and further limiting independent claim 1, should be allowable for that reason as well as the additional recitations each contains. Reconsideration and withdrawal of the rejection of claims 1-4, 7, 13-15 18 and 20 as being anticipated by Sparks is respectfully requested.

Claim Rejections – 35 USC 103

Claims 5 and 6 stand rejected under 35 USC 103(a) as being unpatentable over Sparks (US 5,354,556). As discussed above, claim 1 is neither taught nor fairly suggested by Sparks. Claims 5 and 6, being dependent from and further limiting independent claim 1, should be allowable for that reason as well as the additional recitations each contains. Reconsideration and withdrawal of the rejection of claims 5 and 6 as being unpatentable over Sparks is respectfully requested.

Claims 8-12, 16, 17, 19 and 21-34 stand rejected under 35 USC 103(a) as being unpatentable over Sparks in view of Zema et al. (US 5,306,506). Zema appears to be relied upon by the Examiner for a teaching of microcrystalline cellulose and sodium carboxymethylcellulose, as claimed in independent claim 21.

Applicants submit that Zema does not overcome the deficiencies of Sparks, as discussed above with respect to the claim rejections under 35 USC 102. More specifically, Zema does not teach or fairly suggest a) dry formulation, comprising at least two doses of coated drug particles or b) a core comprising a drug, and a hydrophobic polymer film

coating at least a portion of the core as required by, for example, independent claims 1 and 21. Therefore, without acquiescing to the merits of the Examiner's assertion of what is taught by Zema, Applicants respectfully submit that claims 1 and 21 are not rendered unpatentable by the combination of Sparks and Zema. Applicants respectfully submit that independent claims 1 and 21 should be allowable for at least the same reasons as described above with respect to the claim rejections under 35 USC 102.

Claims 8-12, 16, 17 and 19, being dependent from and further limiting independent claim 1, should be allowable for that reason as well as the additional recitations each contains. Furthermore, claims 22-34, being dependent from and further limiting independent claim 21, should be allowable for that reason as well as the additional recitations each contains.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 8-12, 16, 17, 19 and 21-34 as being unpatentable over Sparks in view of Zema.

CONCLUSION

Applicants believe that, in view of the amendments and remarks made above, this application is in condition for allowance. Early notice to that end is earnestly solicited.

The Commissioner is hereby authorized to charge any additional fees required, or to credit any overpayment to Deposit Account No. 16-1445.

In the event the examiner wishes to discuss any aspect of this response, please contact the attorney at the telephone number identified below.

Respectfully submitted,

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